UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

MAKAYLA HERNANDEZ,

Plaintiff,

v. Case No: 8:20-cv-2409-CEH-JSS

AUROBINDO PHARMA USA, INC.,
and CVS PHARMACY, INC.,

Defendants.
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ORDER

This cause comes before the Court upon Defendant Aurobindo Pharma USA, Inc.'s Motion for Judgment on the Pleadings Pursuant to Federal Rule of Civil Procedure 12(c) (Doc. 35) and Defendant CVS Pharmacy, Inc.'s Motion for Judgment on the Pleadings Pursuant to Fed. R. Civ. P. 12(c) (Doc. 37). Plaintiff Makayla Hernandez, as the personal representative of the estate of Rose Marie Hernandez, responds in opposition (Doc. 43). Aurobindo and CVS reply (Docs. 48, 49). Aurobindo's request for judicial notice (Doc. 73) and CVS's request for judicial notice (Doc. 74) also pend.

After Rose Marie Hernandez ingested her prescribed dosage of Losartan HCTZ 50-12.5 mg oral tablets for the first time, she went into respiratory shock. The next day, she died. Her estate's personal representative brings state-law claims against the alleged manufacturer of the drug and the dispensing pharmacy. Those entities now move for judgment on the pleadings, arguing chiefly that federal law preempts the

claims. The Court agrees. For the reasons set forth below, the Court will grant Aurobindo Pharma USA's Motion for Judgment on the Pleadings and grant CVS Pharmacy's Motion for Judgment on the Pleadings.

I. BACKGROUND

A. Factual Background[1]

In April of 2019, Rose Marie Hernandez received a prescription for Losartan HCTZ 50-12.5 mg oral tablets. Doc. 1-1 ¶17. An angiotensin receptor blocker, this medication is designed to treat high blood pressure by relaxing blood vessels. *Id.* at ¶13. She filled her prescription at a CVS Pharmacy location in Bartow, Florida, where she received a container with thirty Losartan HCTZ 50-12.5 mg oral tablets. *Id.* at ¶18. On April 20, 2019, she ingested her prescribed dosage of these tablets, for the first time, in accordance with her prescription. *Id.* at ¶19. Shortly after ingesting her prescribed dosage, she went into respiratory shock. *Id.* at ¶20. At Bartow Regional Medical Center, her health quickly deteriorated. *Id.* She died on April 21, 2019. *Id.*

Aurobindo Pharma USA, Inc. designed, manufactured, marketed, developed, tested, labeled, promoted, distributed, warranted, and sold their product, Losartan HCTZ 50-12.5 mg oral tablets. *Id.* at ¶7. The Losartan tablets contained boxed warnings, which served to educate and advise the potential user, or the user's prescribing physician, of the potential side effects and adverse reactions related to the

[1] This statement of facts is derived from the complaint, the allegations of which the Court accepts as true in ruling on the motions for judgment on the pleadings. *Perez v. Wells Fargo N.A.*, 774 F.3d 1329, 1335 (11th Cir. 2014).

medication. *Id.* at ¶14. However, the boxed warnings for these Losartan tablets did not contain adequate and sufficient warnings about the associated risk and possibility of death while using the medication. *Id.* at ¶15. Aurobindo marketed, advertised, and distributed Losartan HCTZ 50-12.5 mg oral tablets that were defectively designed, more dangerous than the ordinary customer would expect, and unreasonably unsafe for their intended use when they left Aurobindo's possession. *Id.* at ¶16. The Decedent exercised reasonable prudence and caution when she ingested the Losartan and used the medication in a manner in which Aurobindo knew, or should have known, that the product would be used. *Id.* at ¶21. She did not alter, or cause to be altered, any part of the Losartan HCTZ 50-12.5 mg oral tablets. *Id.* at ¶22.

B. Procedural Posture

Makayla Hernandez, the Decedent's daughter, now brings this action as the personal representative of the Decedent's estate. *Id.* at ¶¶2–4. She lodges the following claims against Aurobindo: (1) "Strict Product Liability – Failure to Warn"; (2) "Negligent Failure to Warn"; (3) "Negligence"; (4) "Wrongful Death"; and (5) "Products Liability – Breach of Implied Warranty of Merchantability." Doc. 1-1 ¶¶23–76. She also sues CVS for: (1) "Strict Product Liability – Failure to Warn"; (2) "Negligent Failure to Warn"; and (3) Wrongful Death. *Id.* at ¶¶77–106.

Aurobindo and CVS answer and assert affirmative defenses (Docs. 17, 32). With the pleadings closed, Aurobindo and CVS move for judgment on the pleadings. (Docs. 35, 37), to which Hernandez responds (Doc. 43). Aurobindo and CVS also

reply (Docs. 48, 49). The Court held oral argument. *See* Doc. 72 at 1. Afterwards, Aurobindo and CVS filed requests for the Court to take judicial notice (Docs. 73, 74).

II. LEGAL STANDARD

When resolving a motion for judgment on the pleadings under Rule 12(c), Fed. R. Civ. P., the Court must consider all of the pleadings: the complaint, the answer, and any documents attached as exhibits. *Eisenberg v. City of Miami Beach*, 54 F. Supp. 3d 1312, 1319 (S.D. Fla. 2014). "Judgment on the pleadings is proper when no issues of material fact exist, and the moving party is entitled to judgment as a matter of law based on the substance of the pleadings and any judicially noticed facts." *Cunningham v. Dist. Attorney's Office for Escambia Cnty.*, 592 F.3d 1237, 1255 (11th Cir. 2010) (internal quotation marks omitted). "In determining whether a party is entitled to judgment on the pleadings, [a court must] accept as true all material facts alleged in the non-moving party's pleading and . . . view those facts in the light most favorable to the non-moving party." *Perez*, 774 F.3d at 1335; *Cunningham*, 592 F.3d at 1255. "If a comparison of the averments in the competing pleadings reveals a material dispute of fact, judgment on the pleadings must be denied." *Perez*, 774 F.3d at 1335. "A motion for judgment on the pleadings is governed by the same standard as a motion to dismiss under Rule 12(b)(6)." *Carbone v. Cable News Network, Inc.*, 910 F.3d 1345, 1350 (11th Cir. 2018).

III. ANALYSIS

A. Statutory and Regulatory Background

"The FDA regulates prescription and [over-the-counter drugs] under the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 301 *et seq.*" *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 510 F. Supp. 3d 1234, 1241 (S.D. Fla. 2020), *appeal filed*, No. 21-10335. Under the FDCA, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of any application filed pursuant to [21 U.S.C. §355(b) or (j)] is effective with respect to such drug." 21 U.S.C. § 355(a).[2] In relevant part, § 355(b) provides that any person who files an application with respect to any drug subject to § 355(a) must submit items from an exhaustive list as part of the application. *Id.* § 355(b)(1)(A). And § 355(j) addresses abbreviated new drug applications. *Id.* § 355(j). Thus, "[a]pplications for FDA approval can be filed in one of two ways: as a new drug application ('NDA') under § 355(b), or as an abbreviated new drug application ('ANDA') under § 355(j)." *Valley Drug Co. v. Geneva Pharms., Inc.*, 344 F.3d 1294, 1296 (11th Cir. 2003).

Under § 355(b), an NDA must include numerous items, such as "full reports of investigations which have been made to show whether such drug is safe for use and whether such drug is effective in use," "a full list of articles used as components of such drug," and "a full statement of the composition of such drug." 21 U.S.C. § 355(b)(1)(A)(i)–(iii). Although "any person" may file an initial NDA under § 355(b), "only those entities deemed 'applicants' may submit changes to approved NDAs,"

[2] "The term 'person' includes individual, partnership, corporation, and association." 21 U.S.C. § 321(e).

Smith v. Teva Pharms. USA, Inc., 437 F. Supp. 3d 1159, 1163 (S.D. Fla. 2020), as the regulations state that "the applicant must notify FDA about each change in each condition established in an approved NDA beyond the variations already provided for in the NDA," 21 C.F.R. § 314.70(a)(1)(i). "A drug approved under the NDA process, commonly referred to as a 'brand-name drug,' is 'listed' by the FDA as having been 'approved for safety and effectiveness.'" *In re Zantac*, 510 F. Supp. 3d at 1241 (quoting 21 U.S.C. § 355(j)(7)). "Following the approval of its NDA, a brand-name drug has a certain period of exclusivity in the marketplace." *Id.* (citing 21 U.S.C. § 355(j)(5)(F)).

Turning to ANDAs, under the Drug Price Competition and Patent Term Restoration Act, known as Hatch-Waxman Amendments, "'generic drugs' can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011) (citing 21 U.S.C. § 355(j)(2)(A)). As a result, manufacturers may "develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug." *Id.* Section 355(j), which addresses ANDAs, states that "[a]ny person" may file "an abbreviated application for the approval of a new drug." 21 U.S.C. § 355(j)(1). Among other requirements, the FDCA generally requires an ANDA to show that the generic drug is the "bioequivalent" of the listed drug and to show that it contains the same active ingredients, employs the same route of administration, contains the same dosage form, and employs the same strength as the listed drug. *Id.* § 355(j)(2)(A)(ii)–(iv).

As for labeling, an NDA must include the applicant's proposed labeling for the drug, *id.* § 355(b)(1)(A)(vi) (requiring the NDA to include "specimens of the labeling proposed to be used for such drug"); 21 C.F.R. § 314.50(c)(2) (requiring the NDA's summary to include the "proposed text of the labeling"), as well an "integrated summary of the benefits and risks of the drug, including a discussion of why the benefits exceed the risks under the conditions stated in the labeling," 21 C.F.R. § 314.50(d)(5)(viii).[3] "The FDA may approve an NDA only if it determines that the drug in question is 'safe for use' under the 'conditions of use prescribed, recommended, or suggested in the proposed labeling thereof.'" *Mutual Pharms. Co., Inc. v. Bartlett*, 570 U.S. 472, 476 (2013) (quoting 21 U.S.C. § 355(d)). "The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); *see* 21 C.F.R. § 314.105(b) ("FDA will approve an NDA and issue the applicant an approval letter on the basis of draft labeling if the only deficiencies in the NDA concern editorial or similar minor deficiencies in the draft labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed, and upon the applicant submitting to FDA a copy of the final printed labeling prior to marketing.).

On the other hand, an ANDA must contain information showing that "the conditions prescribed, recommended, or suggested in the labeling proposed for the

[3] The FDCA defines the term "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

new drug have been previously approved" for a listed drug. 21 U.S.C. § 355(j)(2)(A)(i). An ANDA may not be approved if "information submitted in the application is insufficient to show that the labeling proposed for the drug is the same as the labeling approved for the listed drug . . . except for changes required because of differences approved under a petition filed under [21 U.S.C. § 355(j)(2)(C)] or because the drug and listed drug are produced or distributed by different manufacturers." *Id.* § 355(j)(4)(G). "Labeling (including the container label, package insert, and, if applicable, Medication Guide) proposed for the drug product *must be the same as the labeling approved for the reference listed drug*, except for changes required because of differences approved under a petition filed under [21 C.F.R.] § 314.93 or because the drug product and the reference drug are produced or distributed by different manufacturers." 21 C.F.R. § 314.94(a)(8)(iv) (emphasis added). Unsurprisingly then, an ANDA's approval may be withdrawn if the FDA finds that "the labeling for the drug product that is the subject of the [ANDA] is no longer consistent with that for the listed drug referred to in the abbreviated new drug application," except for limited exceptions inapplicable here. *Id.* § 314.150(b)(10).

Thus, federal drug labeling duties differ. *Mensing*, 564 U.S. at 613. The Supreme Court summarized this difference in terms of drug manufacturers, explaining: "A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," whereas a "manufacturer seeking generic drug approval . . . is responsible for ensuring that its warning label is the same as the brand name's." *Id.* "[W]arning labels of a brand-name drug and its generic copy must always be the

same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'" *Id.* at 613–14 (deferring to the FDA's interpretation); *see Bartlett*, 570 U.S. at 477 ("Generic manufacturers are also prohibited from making any unilateral changes to a drug's label."); *Guarino* v. *Wyeth,* 719 F.3d 1245 (11th Cir. 2013) ("As explained in *Mensing,* generic manufacturers operate under a 'duty of sameness,' which requires that their labels be at all times identical to the brand-name label of the same drug.").

"Once a drug—whether generic or brand name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including active ingredients, or in the specifications provided in the approved application." *Bartlett*, 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i). Where "an applicant seeks 'major changes' to approved drugs, which would have 'a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product,' the FDA must approve the applicant's supplemental NDA before the altered product can be distributed." *Smith*, 437 F. Supp. 3d at 1164 (alteration omitted) (quoting 21 C.F.R. § 314.70(b)(1)). But the changes-being-effected regulation "allow[s] drug changes to generic drug labels only when a generic drug manufacturer changes its label to match an updated brand-name label or to follow the FDA's instructions." *Mensing*, 564 U.S. at 614–15. "CBE changes unilaterally made to strengthen a generic drug's warning label would violate the statutes and regulations requiring a generic drug's label to match its counterparts." *Id.* Finally, "state-law design-defect claims that turn on the adequacy of a drug's warnings are pre-empted by federal law" under *Mensing. Bartlett*, 570 U.S. at 476.

B. Requests for the Court to Take Judicial Notice

1. Applicable Standards

Federal Rule of Evidence 201 "governs judicial notice of an adjudicative fact, not a legislative fact." Fed. R. Evid. 201(a). "The court may judicially notice a fact that is not subject to reasonable dispute because it . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." Fed. R. Evid. 201(b)(2). The Court may take judicial notice on its own. Fed. R. Evid. 201(c)(1).

"Courts in this District and elsewhere regularly take judicial notice of public records available on the FDA's website because such document[s] satisfy the requirements of Rule 201." *Stanifer v. Corin USA Ltd., Inc.*, No. 6:14-cv-1192-RBD-DAB, 2014 WL 5823319, at *3 (M.D. Fla. Nov. 10, 2014) (collecting cases); *see Rounds v. Genzyme Corp.*, No. 8:10-cv-2479-SDM-TBM, 2010 WL 5297180, at *1 (M.D. Fla. Dec. 20, 2010) (holding that "the FDA's public records and statements about [a medical device] merit judicial notice"); *Tinkler v. Mentor Worldwide, LLC*, No. 1:19-cv-23373-UU, 2019 WL 7291239, at *4 n.4 (S.D. Fla. Dec. 30, 2019) ("[I]t is well-settled that the Court can take judicial notice of FDA records located on the FDA's website—a source that cannot reasonably be questioned."). Finally, the Court may take judicial notice in ruling upon a motion for judgment on the pleadings. *See* Fed R. Evid. 201(d).

2. Offered Information

Aurobindo provides, and cites to, records available on the FDA's website to argue that the subject drug is a generic drug. Doc. 73 at 3–7. Similarly, CVS provides, and cites to, records available on the FDA's website to argue that it does not

manufacture the subject drug and that the subject drug is a generic drug. Doc. 74 at 1. Hernandez has not opposed the requests for judicial notice.

i. The Subject Drug is a Generic Drug

Aurobindo provides a document from the FDA's website that discusses ANDAs (Doc. 73-1). In relevant part, the website explains that an ANDA "contains data which is submitted to [the] FDA for the review and potential approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, lower cost alternative to the brand-name drug it references." Doc. 73-1 at 1; U.S. Food & Drug Administration, *Abbreviated New Drug Application (ANDA)*, https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda (last visited Jan. 12, 2022). This record satisfies the requirements of Rule 201. As such, the Court takes judicial notice of this document, which shows that ANDAs are for generic drugs.

Aurobindo and CVS both offer a records search for "losartan" in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" publication. (Docs. 73-2, 74-2). The publication, referred to as the "Orange Book," identifies "drug products approved on the basis of safety and effectiveness by the [FDA] under the Federal Food, Drug, and Cosmetic Act . . . ." U.S. Food & Drug Administration, *Resources for Information | Approved Drugs*, https://www.fda.gov/drugs/drug-approvals-and-databases/resources-information-approved-drugs (last visited Jan. 12, 2022). The search for "losartan" reveals 116 products. Doc. 73-2 at 2–7; Doc. 74-2 at 2. The Court takes judicial notice of the search results because the information satisfies

the requirements of Rule 201. The search reveals the following information. The top three results for products with the active ingredient of "Hydrochlorothiazide; Losartan Potassium" are products with "Hyzaar" listed as the proprietary name and "Organon LLC a sub of Organon and Co" listed as the applicant holder. Doc. 73-2 at 1; Doc. 74-2 at 2. For the remaining products with "Hydrochlorothiazide; Losartan Potassium" listed as the active ingredient, the Orange Book provides "Losartan Potassium and Hydrochlorothiazide" as the proprietary name, with differing strength and varying applicant holders.[4] Doc. 73-2 at 1–2; 74-2 at 2. Also, the Court takes judicial notice of the FDA's explanation on its website that the Orange Book "includes indices of prescription and OTC drug products by proprietary name (brand name or trade name) or, if no proprietary name exists, established name of the active ingredient and by applicant name, which have been abbreviated for th[e] publication." U.S. Food & Drug Administration, *Orange Book Preface*, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Jan. 12, 2022). This fact meets the requirements of Rule 201. Thus, the proprietary name is the brand name or trade name of the drug and, if a proprietary name does not exist, the Orange Book includes indices of drug products by established name of the active ingredient and by applicant name.

[4] Also, the search lists products with "Losartan Potassium" as an active ingredient and products with a "Discn" market status that have "Hydrochlorothiazide; Losartan Potassium" or "Losartan Potassium" as an active ingredient. Doc. 73-2 at 5–7; Doc. 74-2 at 2.

Next, the Orange Book provides the product details for NDA #020387 (distinguishable from an ANDA), which indicates that the NDA is for Hyzaar and that "Organon LLC a sub of Organon and Co" is the applicant holder. Doc. 74-4 at 2; *see also* Doc. 73-4 at 2 (indicating that "Organon" is the "Company" associated with NDA #20387 and listing "Hyzaar" as the "Drug Name" associated with NDA #20387). The Court judicially notices these records. *See* Fed. R. Evid. 201(a)–(b). As such, the Court takes judicial notice that "Organon LLC a sub of Organon and Co" is the applicant holder of an NDA for Hyzaar which, per the earlier search of the Orange Book, is a brand-name product containing "Hydrochlorothiazide; Losartan Potassium" as an active ingredient, and that "Organon" is the "Company" associated with that NDA.

The Orange Book also includes product details for ANDA #091629, which Aurobindo and CVS provide. Doc. 73-3 at 2; Doc. 74-5 at 2. This ANDA lists prescription Losartan Potassium and Hydrochlorothiazide 12.5MG/50MG and prescription Losartan Potassium and Hydrochlorothiazide 25MG/100MG. Doc. 73-3 at 2–3; Doc. 74-5 at 2. Hernandez alleges that her mother ingested "Losartan HCTZ 50-12.5 mg oral tablets." Doc. 1-1 ¶19. The product details under ANDA #091629 for prescription Losartan Potassium and Hydrochlorothiazide 12.5MG/50MG indicate that: "Hydrochlorothiazide; Losartan Potassium" is listed as the active ingredient; "Losartan Potassium and Hydrochlorothiazide" is listed as the propriety name; the ANDA was approved; the strength is 12.5 mg/50 mg; and "Aurobindo Pharma Ltd"

is the applicant holder.[5] Doc. 73-3 at 2; Doc. 74-5 at 2. The Court takes judicial notice of these records. *See* Fed. R. Evid. 201(a)–(b). The earlier Orange Book search for "losartan," discussed above, also lists ANDA #091629 among the search results with "Aurobindo Pharma Ltd" provided as the applicant holder. Doc. 73-2 at 2; Doc. 74-2 at 2. As such, the Court takes judicial notice of the fact that "Aurobindo Pharma Ltd." is the applicant holder for ANDA #091629, which pertains to a drug with the proprietary name of "Losartan Potassium and Hydrochlorothiazide" and with strength of 12.5mg/50mg, which contains the active ingredient of "Hydrochlorothiazide; Losartan Potassium."

CVS provides, and both Aurobindo and CVS cite to, the FDA's "Drugs@FDA" search database for FDA-approved drugs, which is available on the FDA's website. Doc. 73 at 6; Doc. 74 at 8; Doc. 74-6 at 2. In relevant part, searching "losartan" on the database reveals: (1) Cozaar (Losartan Potassium) with NDA #020386; (2) Hyzaar (Hydrochlorothiazide; Losartan Potassium) with NDA #020387; (3) Losartan Potassium with several different ANDA numbers; and (4) Losartan Potassium and Hydrochlorothiazide with several different ANDA numbers, one of which is ANDA #091629, which is associated with "Aurobindo Pharma." Doc. 74-6 at 2. The Court takes judicial notice of these search results. *See* Fed. R. Evid. 201(a)–(b). Also, on its own, the Court takes judicial notice of the fact that "HCTZ" is an abbreviation for

[5] The same information is listed for Losartan Potassium and Hydrochlorothiazide 25MG/100MG. Doc. 74-5 at 2.

"hydrochlorothiazide." Merriam-Webster Dictionary, *Medical Definition of* Hydrochlorothiazide, https://www.merriamwebster.com/dictionary/hydrochlorothiazide#medicalDictionary (last visited Jan. 12, 2022) (defining "hydrochlorothiazide" as "a diuretic and antihypertensive drug $C_7H_8ClN_3O_4S_2$ —abbreviation HCTZ"); *see also Duncan v. Corr. Med. Servs.*, 451 F. App'x 901, 902 (11th Cir. 2012) (abbreviating hydrochlorothiazide as "HCTZ"); *Berkel v. Colvin*, No. 1:12-cv-3558-AJB, 2014 WL 806864, at *2 (N.D. Ga. Feb. 27, 2014) (citing to an online medical database for the proposition that "'HCTZ' is an abbreviation for the diuretic hydrochlorothiazide"). Here, Hernandez alleges that the Decedent was "prescribed the prescription drug Losartan HCTZ 50-12.5 mg . . . ." Doc. 1-1 ¶13. Thus, the judicially noticed information reveals that Organon is the only NDA holder for a Losartan drug with hydrochlorothiazide, also known as "HCTZ," and that such drug is called Hyzaar.[6]

Thus, in sum, this information shows that: (1) Organon is the NDA holder for Hyzaar, the brand-name Losartan Potassium Hydrochlorothiazide drug; (2) Organon is the only NDA holder for a Losartan drug with hydrochlorothiazide, also known as "HCTZ," and that such drug is called Hyzaar; and (3) "Aurobindo Pharma" or "Aurobindo Pharma Ltd." is the ANDA holder of a generic Losartan Potassium and Hydrochlorothiazide drug with strength of 12.5mg/50mg.

[6] The search of the Orange Book for "losartan," which indicates the corresponding NDA number or ANDA number of each of the 116 products, also indicates that Hyzaar is the only drug with "Hydrochlorothiazide; Losartan Potassium" as an active ingredient that has an accompanying NDA.

In ruling on the instant motions, the Court must accept Hernandez's allegations as true and view them in the light most favorable to her. Hernandez refers to the subject drug throughout the complaint as "Losartan HCTZ 50-12.5 mg oral tablets" or "the prescription drug Losartan HCTZ 50-12.5 mg." Doc. 1-1 ¶¶13, 18. Hernandez does not refer to the drug as "Hyzaar," the only brand-name Losartan Potassium Hydrochlorothiazide drug. Hernandez also describes the Losartan HCTZ as "APUSA's Losartan HCTZ 50-12.5mg oral tablets." *Id.* at ¶¶13–15. And Hernandez contends that Aurobindo designed, developed, manufactured, promoted, marketed, labeled, distributed, tested, warranted, and sold this drug. While "Aurobindo Pharma" or "Aurobindo Pharma Ltd." is the ANDA holder of a generic Losartan Potassium and Hydrochlorothiazide drug with strength of 12.5mg/50mg, neither Aurobindo nor CVS address that Hernandez sues Aurobindo Pharma USA, Inc., not "Aurobindo Pharma Ltd." or "Aurobindo Pharma." Nonetheless, Hernandez's allegations clearly associate Aurobindo with the subject drug, not Organon, which is the only NDA holder for a Losartan drug with hydrochlorothiazide. Hernandez also does not refer to the subject drug as "APUSA's Hyzaar," or "Organon's Losartan." Therefore, accepting Hernandez's allegations as true and viewing them in the light most favorable to her indicates that the subject Losartan HCTZ drug at issue is a generic drug.

ii. CVS is Neither an NDA nor an ANDA Holder for Any Losartan Product

CVS also asks the Court to take judicial notice of that fact that "CVS is not a manufacturer of any losartan product, including the losartan at issue in this case . . . ." Doc. 74 at 9. None of the 116 entries in the search of the Orange Book for "losartan"

lists CVS as an applicant holder. Doc. 73-2 at 2–7; Doc. 74-2 at 2. CVS also highlights that the search of "losartan" in the Drugs@FDA database does not show CVS as either an NDA holder or an ANDA holder for any of the listed losartan products. Doc. 74 at 8; Doc. 74-6 at 2. And CVS offers an applicant search of the Orange Book, which reveals that CVS is not the applicant for any FDA-regulated product. Doc. 74-3 at 2.

CVS argues the search results indicate "that CVS is not the manufacturer of any FDA-regulated prescription" and that the Court should take judicial notice of the fact that CVS does not serve as manufacturer of any losartan product. Doc. 74 at 8–9. However, according to the FDA, an applicant holder is not necessarily a manufacturer. On its own, the Court takes judicial notice of the FDA's recognition that "[p]roducts in the Orange Book are identified by the names of the holders of approved applications (applicants) who may not necessarily be the manufacturer of the product, as "[t]here are numerous entities other than the applicant who may be involved in the development, manufacturing, and/or marketing of a product." U.S. Food & Drug Administration, *Orange Book Preface*, https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface (last visited Jan. 12, 2022). Therefore, the fact that CVS is not listed as an applicant holder for any FDA-regulated drug does not show that CVS is not the manufacturer of any FDA-regulated product.

Nonetheless, the FDA records show that CVS is not the NDA holder (or ANDA holder) for any losartan product. The Court takes judicial notice of this fact.

C. Aurobindo's Motion for Judgment on the Pleadings

Aurobindo argues that Counts I through V are failure-to-warn claims because they merely allege that Aurobindo failed to warn the Decedent of the alleged dangers of taking the Losartan HCTZ 50-12.5 mg oral tablets. Doc. 35 at 8. Aurobindo argues that the FDCA governs those claims and that the claims are preempted under *Mensing*.[7] *Id.* at 8–15. As explained below, federal law preempts the claims against Aurobindo.

Under the Supremacy Clause, the Constitution and the laws of the United States "shall be the supreme Law of the Land." U.S. Const. art. VI, cl. 2. The preemption doctrine stems from this Clause, "and any state law the interferes with, or is contrary to, federal law is preempted." *Estrada v. Becker*, 917 F.3d 1298, 1302 (11th Cir. 2019) (internal alterations and quotation marks omitted). Congress may preempt state law through: (1) express preemption; (2) field preemption; or (3) conflict preemption. *Id.* at 1303. "[W]hen state law conflicts with federal law, state law must give way." *Guarino*, 719 F.3d at 1248. "Conflict preemption . . . arises in instances where (1) compliance with both federal and state regulations is a physical impossibility, or (2) the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Fresenius Med. Care Holdings, Inc. v. Tucker*, 704 F.3d 935, 939 (11th Cir. 2013). Preemption is an affirmative defense. *See Metro Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987) ("Federal preemption is ordinarily a federal defense to the plaintiff's suit.").

1. Count I ("Strict Product Liability – Failure to Warn")

[7] Aurobindo has raised preemption as an affirmative defense. Doc. 17 at 4.

Federal law preempts Count I, which Hernandez labels as "Strict Liability – Failure to Warn." The allegations within Count I demonstrate that this claim is a failure-to-warn claim. Hernandez alleges that the Losartan HCTZ 50-12.5 mg oral tablets left Aurobindo's possession in a defective condition—specifically, "the boxed warnings failed to give adequate and sufficient warning to alert" the Decedent or her physicians "about the associated risks and the possibility of death through the use of the Losartan HCTZ 50-12.5 mg oral tablets, thus making the product unreasonably dangerous to its foreseeable users . . . and it remained in the same unaltered defective condition up to the time of the subject incident." Doc. 1-1 ¶26. And in concluding this claim, Hernandez alleges that Aurobindo is strictly liable to her for its failure to provide "adequate and sufficient warnings" regarding the risks and possibilities of death and other injuries. *Id.* at ¶32.

The facts of which the Court took judicial notice indicate that the subject Losartan HCTZ 50-12.5 mg is a generic drug. In her allegations, which the Court must accept as true, Hernandez alleges that Aurobindo manufactures the drug. But *Mensing* counsels that Aurobindo, as an alleged generic-drug manufacturer, is responsible for ensuring that the warning label is the same as the brand-name drug's label. Indeed, as an alleged generic-drug manufacturer, Aurobindo must comply with its ongoing federal duty of sameness. Thus, Aurobindo must ensure that the drug's label is the same as the label for Hyzaar, the relevant brand-name drug. And CBE regulations permit changes to the labels of the Losartan HCTZ 50-12.5 mg tablets only if Aurobindo changes the label to match an updated Hyzaar label or follow the FDA's

instructions. In opposing Aurobindo's motion, Hernandez does not argue that Aurobindo failed to match Hyzaar's label or failed to follow the FDA's instructions.[8] Also, the facts of which the Court took judicial notice indicate that Organon, not Aurobindo, is the NDA holder for Hyzaar. Taken alongside Hernandez's allegations, this recognition also indicates that Aurobindo could not change the drug's label.[9]

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[8] Hernandez generally argues that Aurobindo's duty to warn under Florida law does not conflict with federal law, pointing out that federal regulations "require a generic manufacturer to propose stronger warning labels to the FDA if they believe such warnings are needed." Doc. 43 at 8. As such, Hernandez contends that Aurobindo "had a federal law duty to strengthen the labels if [it] believed such warnings were needed . . . ." *Id.* at 8–9. In *Mensing*, the FDA argued that the Generic Manufacturers were required to propose stronger warning labels to the FDA if they believed that such warnings were needed. 564 U.S. at 616. Then, if the FDA agreed, the agency would have worked with the brand-name manufacturer to create a new label for both the brand-name drug and the generic drug. *Id.* The Generic Manufacturers and the FDA disagreed about whether this alleged duty to strengthen a warning label existed. *Id.* The Supreme Court did not resolve the issue, finding preemption even if that duty existed. *Id.* at 617. The Court explained: "The federal duty to ask the FDA for help in strengthening the corresponding brand-name label, assuming such a duty exists, does not change this analysis. Although requesting FDA assistance would have satisfied the [Generic] Manufacturers' federal duty, it would not have satisfied their state tort-law duty to provide adequate labeling." *Id.* at 619. Indeed, "[s]tate law demanded a safer label; it did not instruct the [Generic] Manufacturers to communicate with the FDA about the possibility of a safer label." *Id.* "If these conjectures [about possible FDA action] suffice to prevent federal and state law from conflicting for Supreme Clause purposes, it is unclear when, outside of expess pre-emption, the Supreme Caluse would have any force." *Id.* at 621. Thus, the Supreme Court did not find that such a duty existed, contrary to Hernandez's argument. Even if such a duty does exist, though, it is insufficient to prevent the conflict between state law and federal law here.

[9] Hernandez also alleges that the defects in the Losartan 50-12.5 mg oral tablets were latent and not readily apparent and that because of its manufacturing, preparation, and composition, the Losartan HCTZ 50-12.5 mg oral tablets failed to perform as safely as an ordinary customer would expect when utilized for intended purposes in a manner reasonably foreseeable by Aurobindo. Doc. 1-1 ¶¶27–28. Given the allegations within Count I that refer to inadequate warnings, the Court construes the "defects" and any problems with "manufacturing, preparation and composition" as referring to the inadequate warnings. *See Ferayorni v. Hyundai Motor Co.*, 711 So. 2d 1167, 1170 (Fla. 4th DCA 1998) (stating that, under the theory of strict products liability in Florida law, "a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning"). Even if the Court construed these

Therefore, although Hernandez sues Aurobindo under Florida law because the boxed warnings failed to afford "adequate and sufficient" warning to the Decedent, altering the warnings was impossible for Aurobindo under federal law. As such, this claim is preempted. *See Guarino*, 719 F.3d at 1249 ("'[A]ny state law duty requiring generic manufacturers to act unilaterally in this area [of labeling] is preempted by federal law.'").

2. Count II ("Negligent Failure to Warn")

Federal law also preempts Count II, which Hernandez labels "Negligent Failure to Warn." Like Count I, the allegations demonstrate that this claim is a failure-to-warn claim. Here, Hernandez alleges that Aurobindo "did not adequately, sufficiently, and/or effectively warn" the Decedent or her physicians "and/or did not adequately, sufficiently, and/or effectively communicate all warnings about the associated risk and possibility of death with the use of the Losartan HCTZ 50-12.5 mg oral tablets." Doc. 1-1 ¶34. The drug's "product warnings" were allegedly "vague, incomplete, or otherwise inadequate" to alert users to the drug's "actual risks." *Id.* at ¶35.

Hernandez identifies Aurobindo's duty as a "a duty to warn consumers or users of the Losartan HCTZ 50-12.5 mg oral tablets of the foreseeable risks associated with the use of the product which are known or, by the exercise of reasonable care, should be known" to Aurobindo. *Id.* at ¶36. By allegedly failing to provide any warning or by

allegations as referring to some type of design defect, the allegations nonetheless fall in the context of failure-to-warn allegations, and federal law preempts state-law design-defect claims that turn on the adequacy of a drug's warnings. *Bartlett*, 570 U.S. at 476.

allegedly providing a warning that was inadequate to sufficiently and effectively warn the Decedent or her physicians of the associated risk and possibility of death when using the subject drug, Aurobindo breached this duty. *Id.* at ¶38. Aurobindo also allegedly breached this duty "by failing to perform, or otherwise facilitate, adequate testing or fail[ing] to reveal and/or conceal[ing] testing performed on the Losartan HCTZ 50-12.5 mg oral tablets." *Id.* at ¶39. As a direct and proximate result of these breaches, the Decedent allegedly sustained injuries and died. *Id.* at ¶40.

Again, as an alleged generic-drug manufacturer, Aurobindo must comply with its ongoing federal duty of sameness. As a result, Aurobindo must ensure that the drug's label is the same as the label for Hyzaar. Organon, not Aurobindo, is the NDA holder for Hyzaar. Therefore, although Hernandez sues Aurobindo under Florida law because the product warnings were allegedly inadequate and Aurobindo breached its duty by failing to provide an adequate warning, altering the warning labels was impossible for Aurobindo under federal law. As such, this claim is preempted.

Hernandez's allegation that Aurobindo breached its failure-to-warn duty by failing to perform adequate testing or failing to reveal, or concealing, testing does not alter this conclusion. First, the Court notes that the allegation uses "and/or" and that failing to reveal or concealing testing pertains to a failure to warn. Second, under Florida negligence law, "[t]he duty to test . . . is a subpart of a manufacturer's duty to design a product with reasonable care, and thus is subsumed in [a plaintiff's] claims for defective design and failure to warn." *Trahan v. Sandoz, Inc.*, No. 3:13-cv-350-MMH-MCR, 2015 WL 2365502, at *7 (M.D. Fla. Mar. 26, 2015) (alterations in

original) (internal quotation marks omitted)). In some instances, failure-to-test allegations "support a larger failure to warn cause of action and, therefore, in cases against generic drug manufacturers, claims premised on those allegations are preempted." *Id.* Here, Hernandez does not set forth a separate cause of action for Aurobindo's allege failure-to-test. Instead, even when accepting this allegation as true and viewing it in the light most favorable to Hernandez, the allegation falls within a claim replete with allegations concerning inadequate warnings. As such, the Court construes this allegation as offered in support of the failure-to-warn allegations within this claim. Therefore, based on the foregoing analysis, federal law preempts Count II.

3. Count III ("Negligence") and Count IV ("Wrongful Death")

Because Counts III and IV are nearly identical, the Court will address them together. Federal law preempts both claims. Hernandez labels Count III as "Negligence" and labels Count IV as "Wrongful Death." A review of these claims reveals that they are based upon Aurobindo's alleged failure-to-warn.

In both claims, Hernandez alleges that Aurobindo maintained two duties: (1) "a duty of reasonable care to refrain from dispersing and/or marketing a product that was likely to cause death or serious injury to foreseeable customers;" and (2) a duty "to refrain from engaging in activities that posed a general threat of harm to others," including the Decedent. Doc. 1-1 ¶¶44–45, 55–56. Further, in both claims, Hernandez grounds the alleged breaches of these duties in inadequate warnings and a failure to warn. In both claims, Hernandez alleges that Aurobindo breached the duties owed to the Decedent when it placed a product on the market that it knew, or should have

known, "would fail to adequately warn of the possibility of death and was unreasonably unsafe to the ordinary consumer." *Id.* at ¶¶46, 57. In Count III, Hernandez alleges that Aurobindo also breached the duties by failing to warn the Decedent of the possibility of death after ingesting the product, whereas she alleges in Count IV that Aurobindo also breached this duty by failing to warn the Decedent of the defective product and failing to warn of the possibility of death after ingestion. *Id.* at ¶¶47, 58. Aside from this slight variation in language, Count III and Count IV are identical. In both claims, Hernandez alleges that Aurobindo knew, or should have known, that "failing to warn an individual of death as a result of ingestion of [Aurobindo's] product" would lead to the Decedent's reasonable and foreseeable use of the drug. *Id.* at ¶¶50, 61.

Like Counts I and II, the allegations indicate that Counts III and IV are premised upon Aurobindo's alleged failure to warn. For the reasons set forth above, including Aurobindo's status as an alleged generic drug manufacturer, the duty of sameness, and Organon serving as the NDA holder of Hyzaar, altering the boxed warning labels was impossible for Aurobindo under federal law. As such, federal law preempts Counts III and IV.[10]

4. Count V ("Products Liability – Breach of Implied Warranty of Merchantability")

Finally, Hernandez's fifth claim—"Products Liability – Breach of Implied Warranty of Merchantability"—is preempted. Under Florida's UCC, "a warranty that

[10] Hernandez's attempt to distinguish between common-law claims and statutory claims is unpersuasive. *See Bartlett*, 570 U.S. at 491 (rejecting such a distinction).

the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." Fla. Stat. § 672.314(1). "A cause of action for breach of implied warranty of merchantability requires allegations that (1) the plaintiff was a foreseeable user of the product, (2) the product was used in the intended manner at the time of the injury, (3) the product was defective when transferred from the warrantor, and (4) the defect caused the injury." *Jovine v. Abbott Labs., Inc.*, 795 F. Supp. 2d 1331, 1340 (S.D. Fla. 2011) (citing *Amorso v. Samuel Friedland Fam.*, 604 So. 2d 827, 833 (Fla. 4th DCA 1992)).

Count V revolves around Aurobindo's alleged breaches of a duty. Hernandez grounds the duty in "ensur[ing] that defective products, such as [the] Losartan HCTZ 50-12.5 mg oral [tablets], were not being distributed, sold, advertised, and/or marketed in a manner that was unreasonably unsafe to the public" and the Decedent. Doc. 1-1 ¶70. Aurobindo allegedly breached this duty by: (1) negligently placing a defective product into the chain of commerce such that it would reach the public in a defective condition; and (2) failing to perform or facilitate adequate testing or failing to reveal or concealing testing performed on the drug. *Id.* at ¶¶72–73. The drug was in a defective condition because it "was defectively designed and in a condition that made [it] unreasonably unsafe for its intended use," thereby "making the product unreasonably dangerous to its foreseeable users and consumers." *Id.* at ¶68. The drug allegedly did not perform as safely as an ordinary consumer would expect it to when used for intended purposes, and in a manner reasonably foreseeable, because of its manufacturing, preparation, and composition. *Id.* at ¶69.

Thus, unlike the other claims against Aurobindo, Count V is not teeming with failure-to-warn allegations. Instead, this claim revolves around Aurobindo's purported duty to ensure that a defective product, which was defective because it was defectively designed and unreasonably unsafe, was not distributed, sold, advertised, or marketed in a manner that was unreasonably unsafe to the public and the Decedent.[11] But "the FDCA requires a generic drug to have the same active ingredients, route of administration, dosage form, strength, and labeling as the brand-name drug upon which it is based." *Bartlett*, 570 U.S. at 483–44. Increasing a product's "usefulness" or reducing its "risk of danger" would require redesigning the drug, as both usefulness and risk of danger are direct results of the drug's chemical design and active ingredients. *Id.* at 483. "Under *Bartlett*, a claim that a generic drug manufacturer's product is unfit for its intended use or unreasonably dangerous is one that would impose a duty to alter the composition of that drug." *Schrock v. Wyeth*, 727 F.3d 1273, 1288 (10th Cir. 2013).

Numerous courts have found breach-of-implied-warranty claims like this claim preempted. *See*, *e.g.*, *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 935 (6th Cir. 2014) (affirming the district court's dismissal of the plaintiffs'

[11] Because this claim identifies the drug's "defective condition" as its defective design and unreasonably unsafe condition and Hernandez grounds the duty in ensuring that defective products were not distributed, sold, advertised, or marketed to the public, the Court, when accepting Hernandez's allegations as true and viewing them in the light most favorable to her, construes her allegation that the drug failed to perform as safely as an ordinary customer would expect because of its "manufacturing, preparation and composition" to refer to the drug's allegedly defective design.

implied-warranty claims as preempted because the claims, which stemmed from the generic manufacturers' continued marketing of the product, were based on the drug's allegedly defective design); *In re Pamidronate Prods. Liab. Litig.*, 842 F. Supp. 2d 479, 485 (E.D.N.Y. 2012) (finding the plaintiffs' breach-of-warranty claims preempted, in which the plaintiffs alleged that the drug was not of a merchantable quality nor safe or fit for its intended uses in contravention of the defendants' implied warranty, because "this cause of action is founded on the argument that [the drug] should have been designed differently"); *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig. (No. II)*, No. 08-008(GEB-LHG), 2011 WL 5903623, at *8 (D.N.J. Nov. 21, 2011) (holding that the plaintiffs' breach-of-warranty claims were preempted where they alleged that the drug was unreasonably dangerous because "this cause of action is reliant on the argument that [the drug] should have been designed differently"). And Aurobindo could not escape any impossibility by choosing "not to make [the drug] at all." *Bartlett*, 570 U.S. at 487 (internal quotation marks omitted).

Further, Count V includes Hernandez's allegation from the complaint's factual statement that the boxed warnings for the Losartan HCTZ 50-12.5 mg oral tablets did not contain adequate or sufficient warnings about the associated risk, and possibility of death, with the medication's usage. During oral argument, the Court asked Hernandez's counsel to identify the actions or omissions upon which Count V is based. Hernandez's counsel responded that Count V is grounded upon the fact that Aurobindo had information about a death in 2016 and did not warn the FDA. As discussed above, the Supreme Court has held that any federal duty to ask the FDA for

help in strengthening a corresponding brand-name label does not change the preemption analysis. To the extent that Hernandez predicates this claim upon an alleged failure to warn, federal law preempts the claim for the reasons discussed above. *See Guarino*, 719 F.3d at 1249 (holding that federal law preempted each of the plaintiff's claims, including a claim for "breach of warranty," because each claim was "premised upon an allegedly inadequate warning").

Therefore, federal law preempts the claims against Aurobindo.

D. CVS's Motion for Judgment on the Pleadings

CVS argues that federal law preempts Hernandez's three claims against CVS. Doc. 37 at 6–16. CVS also asserts that those claims fail under Florida law.[12] *Id.* at 17–23. The Court agrees.

1. Count VI ("Strict Product Liability – Failure to Warn")

Federal law preempts Count VI, which Hernandez labels as "Strict Product Liability – Failure to Warn." Hernandez alleges that the Losartan HCTZ 50-12.5 mg oral tablets left CVS's possession in a defective condition in that they were "in a condition that made the product unreasonably unsafe for its intended use, thereby "making the product unreasonably dangerous to its foreseeable users and customers." Doc. 1-1 ¶80. The alleged "defects" in the Losartan HCTZ 50-12.5 mg oral tablets were "latent and not readily apparent." *Id.* at ¶81. And because of the drug's "negligent manufacturing, preparation and/or composition," the Losartan HCTZ 50-12.5 mg

[12] CVS has raised both preemption and failure-to-state-a-claim as affirmative defenses. Doc. 32 at 24, 28.

oral tablets allegedly failed to perform as safely as an ordinary consumer would expect them to when used for their intended purposes in a manner reasonably foreseeable by CVS. *Id.* at ¶82. "Under the theory of strict products liability adopted [by the Florida Supreme Court], a product may be defective by virtue of a design defect, a manufacturing defect, or an inadequate warning." *Ferayorni*, 711 So. 2d at 1170. The allegations indicate that Hernandez bases Count VI upon CVS's alleged failure to warn. Within this claim, Hernandez alleges that the drug "failed to warn foreseeable consumers of the possibility of risk and death." Doc. 1-1 ¶80. She alleges that CVS is strictly liable to her "for its failure to provide adequate and sufficient warnings." *Id.* at ¶85. As such, Count VI is a strict liability failure-to-warn claim against CVS.[13]

However, as alleged, CVS simply operates multiple pharmacies in Florida, was in the business of distributing and selling pharmaceuticals, including the Losartan HCTZ 50-12.5 mg oral tablets, and the Decedent filled her prescription at a CVS location in Florida. Hernandez does not allege that CVS is a manufacturer of the specified drug. The facts of which the Court took judicial notice indicate that CVS is not the NDA holder (or ANDA holder) for any losartan product. Thus, altering either the drug's label or design was impossible for CVS under federal law because CVS lacked the ability to do so.

[13] Given the allegations within Count VI that reference inadequate warnings, the Court construes the "negligent manufacturing, preparation and/or composition" as referring to the inadequate warnings.

Numerous courts applying the preemption analysis have found that federal law preempted claims based upon improper labeling or defective design when the defendant lacked the ability to alter the drug's label or design. *See*, *e.g.*, *In re Zantac*, 510 F. Supp. 3d at 1250–51 (finding that federal law preempted the plaintiffs' state-law claims against the distributors and retailers, which were based upon the subject drug's allegedly defective design and "inadequate labels/warnings," because the defendants "ha[d] no ability to alter a label or alter a drug's design"); *Greager v. McNeil-PPC, Inc.*, 414 F. Supp. 3d 1137, 1142 (N.D. Ill. 2019) (finding the plaintiff's state-law claims against a manufacturer and a seller of a generic drug preempted and noting that the "key distinction in the relevant regulatory structure and case law" is "between NDA holders and ANDA holders" and that this distinction "makes a difference because of the [CBE] regulation, which permits NDA holders—but not ANDA holders—to 'add or strengthen' a warning on the product's label . . . without waiting for preapproval from the FDA"); *In re Lipitor (Atorvastatin Calcium) Marketing, Sales Practices & Prods. Liab. Litig.*, MDL No. 2:14-mn-2502-RMG, 2016 WL 7368203, at *2 (D.S.C. Nov. 1, 2016) (finding claims against a defendant-pharmacy based on a drug's label preempted under *Mensing* and noting that, "[a]s a result of the scheme set forth by the Federal Drug and Cosmetic Act (FDCA), a pharmacy also has no authority to unilaterally change a drug's label"); *see also Smith*, 437 F. Supp. 3d at 1165 (explaining that the FDA's regulations do not "contemplate a distributor of a brand drug, albeit a distributor closely affiliated with the NDA holder, initiating changes to an approved NDA" and finding "no reason to depart from the wealth of authority clearly stating

that a company that does not hold an NDA, regardless of its connection to the NDA holder, is powerless to submit label changes to the FDA").

Hernandez has not cogently addressed or rebutted this authority, even though CVS cites to several of these cases. Instead, while discussing Count VI during oral argument, Hernandez's counsel argued for the first time that the alleged failure to warn was actually a "failure to act." Hernandez's counsel also mentioned this "failure to act" when discussing failure to warn generally, arguing that the alleged failure to warn was a "failure to act" based on "knowledge." Hernandez's attempt to distinguish a failure to warn from a failure to act is unpersuasive. *See Guarino*, 719 F.3d at 1249 (rejecting the appellant's attempt to distinguish her failure-to-warn claims as "failure-to-communicate" claims because "[n]o matter the garb in which [the appellant] attempts to present them, [her] claims are at bottom allegations regarding Teva's failure to warn her of the dangers of long-term metoclopramide use, and they therefore cannot escape *Mensing*'s grasp"). Therefore, federal law preempts this claim.

Separately, this strict-liability failure-to-warn claim also fails under Florida law. Again, Hernandez alleges the Decedent filled her prescription for Losartan HCTZ 50-12.5 mg oral tablets with CVS. But Florida law does not recognize a claim sounding in strict liability against a pharmacy. In *McLeod v. W.S. Merrell Co., Division of Richardson-Merrell, Inc.*, the Florida Supreme Court held that the "concept of strict liability without fault should not be applied to the prescription druggists in the instant situation," where the patient-purchaser sued for breach of implied warranties, because the consumer's rights could be preserved, and the retail prescription druggist's

responsibilities could be imposed, through warranties. 174 So. 2d 736, 739 (Fla. 1965). The court noted that although the claim was presented as breach of implied warranties, "the real theory" upon which the court was invited to rely was "the rapidly evolving concept of strict liability without fault" and that the "obvious effect of the application of this concept," if the court accepted it, "would be to convert the retail prescription druggists into insurers of the safety of the manufactured drug." *Id. See Oleckna v. Daytona Discount Pharmacy*, 162 So. 3d 178, 181 (Fla. 5th DCA 2015) (stating that *McLeod* considered whether a pharmacy could be held strictly liable for its failure to warn a customer of the possible dangers of using a dispensed drug under a doctor's prescription and rejecting any imposition of strict liability); *Fontanez v. Parental Therapy Assocs., Inc.*, 974 So. 2d 1101, 1104 (Fla. 5th DCA 2007) ("When a pharmacist merely resells a drug that he or she has received from a manufacturer, the pharmacist is playing no role in the preparation of the product, but is simply dispensing the drug. The *McLeod* court found that the imposition of strict liability on a pharmacist simply dispensing a prescription drug would improperly convert retail pharmacists into insurers of the safety of the manufactured drug."); *see also Clay v. Wyeth*, No. 5:04-cv-WTH-GRJ, 2004 WL 7330338, at *2 (M.D. Fla. Aug. 17, 2014) ("[A]lthough Florida courts have extended strict liability to retailers, they have refrained from applying the doctrine to prescription druggists.").

Therefore, in addition to federal law preempting this strict-liability failure-to-warn claim against CVS, the claim also fails under Florida law.

2. Count VII ("Negligent Failure to Warn")

Federal law also preempts Count VII, which Hernandez labels as "Negligent Failure to Warn." Similar to Count II, Hernandez alleges that CVS "did not adequately, sufficiently, and/or effectively warn" the Decedent or her physicians "and/or did not adequately, sufficiently, and/or effectively communicate all warnings about the associated risk and possibility of death with the use of the Losartan HCTZ 50-12.5 mg oral tablets." Doc. 1-1 ¶87. The drug's "product warnings" were allegedly "vague, incomplete, or otherwise inadequate" to alert users to the "actual risks" of the drug. *Id.* at ¶88. CVS had a duty to warn users of the Losartan HCTZ 50-12.5 mg oral tablets of the foreseeable risks associated with the use of the product that were known or reasonably should have been known to CVS. *Id.* at ¶89. CVS allegedly breached this duty by: (1) "failing to provide any warning or by providing a warning that was inadequate to sufficiently and effectively warn" the Decedent or her physicians of the associated risk and possibility of death and (2) "failing to perform, or otherwise facilitate, adequate testing or fail[ing] to reveal and/or conceal[ing] testing performed on the Losartan HCTZ 50-12.5 mg oral tablets." *Id.* at ¶¶91–92. Accepting the allegations as true and viewing them in the light most favorable to Hernandez, the Court construes this claim as a failure-to-warn claim.[14] Because this claim, like Count

[14] For the same reasons articulated above in discussing Hernandez's allegation in Count II concerning Aurobindo's alleged failure to perform adequate testing or failing to reveal, or concealing, Hernandez's allegation here that CVS breached its duty to warn by failing to perform adequate testing or failing to reveal, or concealing, testing does not alter the Court's conclusion that this claim is a failure-to-warn claim.

VI, is premised upon CVS's alleged failure-to-warn, federal law preempts the claim for the reasons discussed above.

Additionally, Count VII fails to state a claim under Florida law. "A pharmacy must use due and proper care in filling a prescription." *Dee v. Wal-Mart Stores, Inc.*, 878 So. 2d 426, 247 (Fla. 1st DCA 2004). "When a pharmacy fills a prescription which is unreasonable on its face, even though it is lawful as written, it may breach this duty of care." *Id.* Nonetheless, in Florida, "a negligence cause of action against a pharmacist or pharmacy may not be premised on a duty to warn nor of the dangerous propensities of a particular prescription drug." *Layton v. SmithKline Beecham Corp.*, No. 8:05-cv-2107-JSW-EAJ, 2006 WL 2194498, at *2 (M.D. Fla. Aug. 2, 2006) (citing *Johnson v. Walgreen Co.*, 675 So. 2d 1036, 1037–38 (Fla. 1st DCA 1996)). "It is well settled under Florida law that while a manufacturer of prescription drugs has a duty to warn of the dangerousness of the drug to members of the medical community lawfully authorized to prescribe, dispense, and administer prescription drugs, that duty is not extended to retail prescription druggists." *Clay*, 2004 WL 7330338, at *9. Because Hernandez bases this negligent failure-to-warn claim upon a pharmacy's alleged failure to warn, or provide an adequate warning, about the associated risk and possibility of death with the use of the subject drug, this claim fails under Florida law.

3. Count VIII ("Wrongful Death")

Finally, federal law also preempts Count VIII, which Hernandez labels as a claim for "Wrongful Death." Here, Hernandez alleges CVS owed two duties: (1) a duty of reasonable care to refrain from dispersing or marketing Losartan HCTZ 50-

12.5 mg oral tablets that were likely to cause death or serious injury to users; and (2) a duty to refrain from engaging in activities that posed a general threat of harm to others, including the Decedent. Doc. 1-1 ¶¶97–98. CVS allegedly breached these duties in two ways: (1) when it placed a drug on the market that it knew or should have known was defectively designed, failed to warn of its dangerous condition, and was unreasonably unsafe to the ordinary consumer; and (2) by failing to warn the Decedent of the defective condition of the Losartan HCTZ 50-12.5 mg oral tablets and the possibility of death after ingestion. *Id.* at ¶¶99–100. Thus, this claim for "Wrongful Death" is broader than the claim for "Wrongful Death" against Aurobindo.

Nonetheless, the second breach is grounded in CVS's alleged failure to warn and part of the first breach is grounded in a failure to warn. For the reasons discussed in finding that federal law preempts Counts VI and VII, federal law preempts this claim to the extent that it is based upon a failure to warn. As for Hernandez's allegation that CVS breached its duties when it placed the drug on the market when it knew, or should have known, that the drug was defectively designed and was unreasonably unsafe, this portion of the claim is also preempted. Even when assuming that this design defect and unreasonably unsafe condition does not refer to the inadequate warnings, federal law preempts this claim. As discussed above in Count V, reducing a drug's risk of danger would require redesigning the drug, and, under *Bartlett*, a claim that a generic drug manufacturer's product is unreasonably dangerous would impose a duty to alter the drug's composition. Because CVS does not hold an NDA, it may not alter the drug's composition. *See In re Zantac*, 510 F. Supp. 3d at 1250–51 (concluding that the

plaintiffs' state-law claims were preempted because each one was based upon the drug's "allegedly defective design and inadequate labels/warnings" and noting that the defendants had no ability to alter the drug's design or label). And any argument that CVS should have stopped selling the drug is unavailing. *See Bartlett*, 570 U.S. at 488 ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability."). As such, federal law preempts this claim.

Count VIII also fails to state a claim under Florida law. "When the death of a person is caused by the wrongful act, negligence, default, or breach of contract or warranty of any person . . . and the event would have entitled the person injured to maintain an action and recover damages if death had not ensued, the person . . . that would have been liable in damages if death had not ensued shall be liable for damages as specified in this act notwithstanding the death of the person injured, although death was caused under circumstances constituting a felony." Fla. Stat. § 768.19. Although Florida's Wrongful Death Act creates a "new and distinct right of action" from the right of action that the Decedent had before death, "courts have also characterized wrongful death actions as derivative because they are dependent upon a wrong committed against the decedent." *Laizure v. Avante at Leesburg, Inc.*, 109 So. 3d 752, 759–60 (Fla. 2013). "No Florida decision has allowed a survivor to recover under the wrongful death statute where the decedent could not have recovered." *Id.* (internal

quotation marks omitted). "In other words, recovery is precluded if the decedent could not have maintained an action and recovered damages if death had not ensued." *Id.*

As alleged, the Decedent could not have brought this claim because federal law preempts it. Further, as explained above, the other claims against CVS fail. Thus, because the Decedent could not have recovered against CVS, this claim fails under Florida law. Courts have dismissed derivative wrongful-death claims where underlying claims against a defendant fail. *See*, *e.g.*, *In re Darvocet*, 756 F.3d at 936 (finding that the district court did not err in dismissing the derivative claims for wrongful death, which "stand or fall with the underlying claims on which they rest," because the district court correctly dismissed the underlying claims); *In re Zantac*, 510 F. Supp. 3d at 1261 (dismissing a derivative wrongful-death claim because the Court dismissed all underlying claims against the defendants).

As such, the claims against CVS are preempted and fail under Florida law.

IV. CONCLUSION

Based on the foregoing analysis, federal law preempts Hernandez's claims. Hernandez's claims against CVS also fail under Florida law. Therefore, the Court will grant the motions for judgment on the pleadings.

Accordingly, it is hereby **ORDERED AND ADJUDGED**:

1. Defendant Aurobindo Pharma USA, Inc.'s Request to Take Judicial Notice of the Fact that the Losartan HCTZ at Issue is a Generic Product (Doc. 73) and Defendant CVS Pharmacy, Inc.'s Request for Judicial Notice (Doc. 74) are each **GRANTED** to the extent explained herein.

2. Defendant Aurobindo Pharma USA, Inc.'s Motion for Judgment on the Pleadings Pursuant to Federal Rule of Civil Procedure 12(c) (Doc. 35) is **GRANTED**.
3. Defendant CVS Pharmacy, Inc.'s Motion for Judgment on the Pleadings Pursuant to Fed. R. Civ. P. 12(c) (Doc. 37) is **GRANTED**.
4. The Clerk is directed to enter **JUDGMENT** on Counts I, II, III, IV, and V in favor of Defendant Aurobindo Pharma USA, Inc. and against Plaintiff Makayla Hernandez, as the Personal Representative of the Estate of Rose Marie Hernandez.
5. The Clerk is directed to enter **JUDGMENT** on Counts VI, VII, and VIII in favor of Defendant CVS Pharmacy, Inc. and against Plaintiff Makayla Hernandez, as the Personal Representative of the Estate of Rose Marie Hernandez.
6. The Clerk is directed to terminate all deadlines and to **CLOSE** this case.

DONE AND ORDERED in Tampa, Florida on January 24, 2022.

Charlene Edwards Honeywell
Charlene Edwards Honeywell
United States District Judge

Copies to:
Counsel of Record and Unrepresented Parties, if any